

---

## IDEC 131: adverse reactions

Various toxicities

In patients with relapsing-remitting multiple sclerosis

---

### Study Details

#### Purpose

This study investigated the tolerability of IDEC 131 [ $\alpha$ CD154] in patients with relapsing-remitting multiple sclerosis.

#### Details

Design: sequential  
Control: baseline comparison, drug dosage comparison  
Phase: Phase I  
Concomitant Medication: None

#### Subjects

| Type     | No. | Sex | Age        |
|----------|-----|-----|------------|
| patients | 12  |     | not stated |

---

### Treatments

#### IDEC 131 (1 mg/kg)

| Drug/Treatment | Dose         | Route      | Frequency | Duration |
|----------------|--------------|------------|-----------|----------|
| IDEC 131       | 1 mg/kg/dose | not stated | 2/week    | 4 doses  |

#### IDEC 131 (5 mg/kg)

| Drug/Treatment | Dose         | Route      | Frequency | Duration |
|----------------|--------------|------------|-----------|----------|
| IDEC 131       | 5 mg/kg/dose | not stated | 2/week    | 4 doses  |

#### IDEC 131 (10 mg/kg)

| Drug/Treatment | Dose          | Route      | Frequency | Duration |
|----------------|---------------|------------|-----------|----------|
| IDEC 131       | 10 mg/kg/dose | not stated | 2/week    | 4 doses  |

#### IDEC 131 (15 mg/kg)

| Drug/Treatment | Dose          | Route      | Frequency | Duration |
|----------------|---------------|------------|-----------|----------|
| IDEC 131       | 15 mg/kg/dose | not stated | 2/week    | 4 doses  |

---

### Results

Multiple doses of IDEC 131 at 1 mg/kg, 5 mg/kg, 10 mg/kg and 15 mg/kg were found to be safe in all patients. Fifteen adverse events were reported of mild to moderate severity which were considered to be possibly treatment-related. IDEC 131 was not associated with any evidence of toxicity as assessed by the Expanded Disability Status Scale, laboratory parameters, relapse rate and other clinical indications.

---

## Adis Assessment

### Study Messages

- IDEC 131 at a dosage of 1 mg/kg, 5 mg/kg, 10 mg/kg or 15 mg/kg is generally well tolerated in patients with relapsing-remitting multiple sclerosis.

### Adis Evaluation

Trial Design:

Clinical            Provides new evidence of clinical benefit and has major implications for a  
Relevance:        patient population.

---

## Reference

Fadul CE, Ryan KA, Noelle RJ, Wishart HA, Saykin AJ, et al. Therapeutic intervention of multiple sclerosis with a CD40 ligand antagonist: a phase I clinical trial. *Neurology* 60 (Suppl. 1): 84, 11 Mar 2003  
Lebanon, New Hampshire, USA

---

© Adis Data Information BV 2003

**Fax Message**

|                 |   |
|-----------------|---|
| To              | Dr Stephanie R Amoroso  |
| Company         | Darby & Darby   |
| Fax number      | 00 1 212 753 6237   |
| Matter          | European Patent Application No. 99915237.4<br>Trustees of Dartmouth College |
| Your ref        | 20052/2200517-EP4   |
| From            | Mr J N Daniels  |
| Our ref         | 103011/JND/SV   |
| Date            | 24 March 2005   |
| Number of pages | (Including this one) <b>7</b>   |

- ☒ Original will follow by post
- ☐ Original will not follow by post

**Page White  
and Farrer**

Patent and  
Trade Mark Attorneys

**UK**  
54 Doughty Street  
London  
WC1N 2LS  
Tel +44(0)20 7831 7929  
Fax +44(0)20 7831 8040  
london@pagewhite.com

**Finland**  
Runeberginkatu 5  
10<sup>th</sup> Floor  
FIN-00100 Helsinki  
Tel +358 9 343 6510  
Fax +358 9 343 6511  
helsinki@pagewhite.com

www.pagewhite.com

Directors:  
P D Jenkins  
Mrs V R Driver  
J N Daniels  
Ms K C Style  
Ms N Shackleton  
P R Slingsby  
C M Hill  
J P Ruuskanen  
J P Cornish  
D J Williams

Associate Directors:  
M N Evans  
Miss J H Evenson  
Miss C A Wolfe

Mrs A E Campbell

Consultant:  
D J Richards

**Confidentiality Notice**

This fax is intended only for the individual or entity to which it is addressed and may contain confidential or privileged information. If you are not the intended recipient you are hereby notified that any copying, dissemination or distribution of the communication is prohibited. If you have received this communication in error please notify us by telephone or fax and return the original to us at the above address by post.

Registered at the above  
London address No. 1319458  
and in Finland  
No. Y-1749026-1